REMARKS

Claims 1-15 are pending in the instant application. Claims 1, 2 and 8-15 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 3-7 have been rejected. Claims 3-7 have been amended. Support for these amendments is provided in the specification at page 1, lines 17-20, page 3, lines 9-27, page 4, lines 5-10, page 14, lines 20-23, and page 16, lines 11-29. Thus, no new matter has been added. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed October 30, 2002. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled without prejudice non-elected claims 1, 2 and 8-15. In light of the finality of this Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Rejection of Claims 3-7 under 35 U.S.C. § 112, first paragraph - Written Description

Claims 3-7 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. Specifically, the Examiner suggests that the written description in this case only sets forth a BSG as SEQ ID NO:4 and not variants, analogs or derivatives of SEQ ID NO:4.

Therefore, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to delete any reference to variants, analogs or derivatives. Instead, in accordance with the teachings of the specification at, for example, page 3, lines 12-27, page 4, lines 5-10, page 14, lines 20-23, and page 16, lines 11-29, Applicants have amended the claims to specify that the BSG comprises a polynucleotide of SEQ ID NO:4, a polynucleotide encoding the same polypeptide as encoded by SEQ ID NO:4 or a protein encoded thereby.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

III. Rejection of Claims 3-6 under 35 U.S.C. § 112, first paragraph - Lack of Enablement

Claims 3-7 have been rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants respectfully traverse this rejection.

At the outset, Applicants respectfully point out that the claims have been amended and are no longer drawn to use of variants of SEQ ID NO:4. Accordingly, the Examiner's comments with respect to enablement of variants of SEQ ID NO:4 are not relevant to the invention as claimed.

Further, Applicants respectfully disagree with the Examiner's suggestion that supporting evidence indicative of SEQ ID NO:4 being a unique tumor or molecular marker for breast cancer is not provided in the instant specification.

As shown in Table 9 at page 87 of the instant application and taught at page 88 of the instant application, 33% of the mammary gland cancer samples tested showed increased expression of SEQ ID NO:4 as compared to control samples. Thus, the sensitivity of this

marker is actually greater than many useful cancer therapeutics and diagnostics that have been FDA approved and are commercially available. For example, Genentech's product Herceptin and its diagnostic counterpart, the HercepTest are very successful commercially. Yet many publications show the relevant gene, HER-2, is overexpressed in only 30% of breast cancer patients. Hence, the sensitivity of the BSG of SEQ ID NO:4 claimed in the instant application is clearly sufficient for predictable diagnostic and monitoring uses with breast cancer.

Accordingly, withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

IV. Rejection of Claims 3-7 under 35 U.S.C. § 112, second paragraph

Claims 3-7 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that recitation of "BSG" is vague and indefinite. Thus, in accordance with the Examiner's suggestion, Applicants have amended the claims to list the full terminology before this acronym in its initial citing in each claim. Support for this amendment is provided in

the specification at page 1, lines 17-20 and page 3, lines 9-12.

Withdrawal of this rejection is therefore respectfully requested.

V. Rejection of Claims 3-7 under 35 U.S.C. § 101

Claims 3-7 have been rejected under 35 U.S.C. § 101 because the Examiner suggests that the claimed invention is not supported by either a specific, substantial, credible or asserted utility or a well-established utility. Specifically, the Examiner suggests that no information is provided supporting the use of SEQ ID NO:4 as a specific tumor marker.

Applicants respectfully traverse this rejection.

As discussed in Section III, supra, Table 9 at page 87 of the instant application and page 88 of the instant application teach that 33% of the mammary gland cancer samples tested showed increased expression of SEQ ID NO:4 as compared to control samples. Thus, the sensitivity of this marker is actually greater than many useful cancer therapeutics and diagnostics that have been FDA approved and are commercially available. For example, Genentech's product Herceptin and its diagnostic counterpart, the HercepTest are very successful commercially. Yet many publications show the relevant gene, HER-2, is overexpressed in only 30% of breast cancer

in only 30% of breast cancer patients. Hence, the sensitivity of the BSG of SEQ ID NO:4 claimed in the instant application is clearly sufficient to establish the utility of this marker in diagnostic and monitoring methods for breast cancer.

Withdrawal of this rejection under 35 U.S.C. § 101 is therefore respectfully requested.

VI. Supplemental IDS

Applicants are submitting herewith a Supplemental Information Disclosure Statement with paper copies of relevant portions of references cited therein and the requisite fee.

VII. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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